PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 107475 a/ubr	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2005/002180	International filing date *(day/month/year)* 02.03.2005	Priority date *(day/month/year)* 02.03.2004
International Patent Classification (IPC) or both national classification and IPC INV. A61B17/04		
Applicant SHERWOOD SERVICES AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.12.2005	26.06.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Angeli, M Telephone No. +49 89 2399-7253

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP2005/002180

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-39 as originally filed

Claims, Numbers

1-16 filed with the demand

Drawings, Sheets

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-6,16
	No:	Claims	1-3,7-15
Inventive step (IS)	Yes:	Claims	4-6,16
	No:	Claims	1-3,7-15
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I.

The amendment of claim 1 is considered as going beyond the disclosure as originally filed. The feature which has been introduced into originally filed claim 1 has only been disclosed with respect to an insertion needle which comprises an elongate aperture in its wall surface facing a retrieval needle shaft and said retrieval needle shaft which comprises an aperture in its wall surface facing the insertion needle shaft, whereas the insertion needle lumen contains said engaging portion and the engaging portion is an elongate lock part long enough to bridge across from the insertion needle aperture to the retrieval needle aperture.

These features are indispensable and essential for the proper functioning of the invention and for being carried out by the person skilled in the art. Further, the subject-matter is broadened to possible embodiments, which have not been disclosed in the original application as filed.

Therfore, the International Preliminary Examination Report has been based on originally filed claims 1-16 (Rule 70.2(c) PCT).

Re Item V.

1 Reference is made to the following documents:

D1: US-B1-6 638 286 (BURBANK FRED ET AL) 28 October 2003 (2003-10-28)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. There is no difference between the subject-matter of claim 1 and D1.
Document D1 discloses (the references in parentheses applying to this document):

A medical tool suitable for suturing comprising: an insertion puncture needle (reference 120) formed with an insertion hole from the proximal end to the distal end; a retrieval puncture needle (reference 122) disposed substantially in parallel with the insertion puncture needle at a predetermined distance therefrom; and a surgical

suture (column 7, line 42; reference 154) extending from the proximal end of the insertion puncture needle through the distal end and then engaged with the distal end of the retrieval puncture needle via an engaging portion (column 11, line 4; reference 262).

3 DEPENDENT CLAIMS 2-3,7-15

Dependent claims 2-3,7-15 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

3.1 Claim 2: The wording "lower end of the engaging member" is too vague in order to delimit the claimed subject-matter from the prior art (Article 6 PCT). Therefore the portion of the engagement member 262 in D1 is also regarded as being connected to the suture at the lower end. Further, an essential feature is missing defining the actuation of the engagement member and the reason for the connection of the suture to the "lower end", e.g. as defined in claim 16 (PCT/GL/ISPE/1, Page 48, Paragraph 5.55).

3.2 Claim 3: See column 11, line 7; reference 264.

4 DEPENDENT CLAIM 4

4.1 The elongate portion having a wider upper portion and a narrow lower portion is not disclosed in D1 (Article 33(2) PCT). The effect is to be seen in the engagement member that is movable in a predefined direction without the need of further supplemental parts.

5 INDEPENDENT CLAIM 16

5.2 Document D1, which is considered to represent the most relevant state of the art, differs from the subject-matter of claim 16 in that:
the insertion needle contains a suture which is attached to the lock part whereby pulling on the suture causes the lock part to emerge from the insertion needle lumen and extend across to the retrieval needle aperture so that, with withdrawal of the retrieval needle, the suture is advanced from the puncture made by the insertion

needle to the puncture made by the retrieval needle.

5.3 The subject-matter of claim 16 is therefore novel (Article 33(2) PCT). The problem to be solved by the present invention may be regarded as:
Facilitating the actuation mechanism and the reliability of the capturing mechanism.

5.4 The solution to this problem proposed in claim 16 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
Non of the cited documents gives a hint of using the suture in order to activate an engagement member.

PCT/EP2005/002180
SHERWOOD SERVICES AG

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C L A I M S

1. A medical suturing tool comprising:

an insertion puncture needle formed with an insertion hole from the proximal end to the distal end;

a retrieval puncture needle disposed substantially in parallel with the insertion puncture needle at a predetermined distance therefrom; and

a surgical suture extending from the proximal end of the insertion puncture needle through the distal end and then engaged with the distal end of the retrieval puncture needle via an engaging portion whereby pulling on the suture causes the engaging portion to emerge from the insertion needle and extend across to the retrieval needle so that, with withdrawal of the retrieval needle, the suture is advanced from the puncture made by the insertion needle to the puncture made by the retrieval needle.

2. A tool according to Claim 1, comprising: an elongate opening provided on a surface of the insertion puncture needle opposing to the retrieval puncture needle in communication with the insertion hole; an engaging member being capable of moving in the insertion hole of the insertion puncture needle and, when having reached a predetermined position in the insertion hole, bending from the side of the upper end portion thereof to project outside from the elongate opening; and an engaging groove provided on a surface of the retrieval puncture needle opposing to the insertion puncture needle, wherein the surgical suture is connected to the lower end of the engaging member so that the

suturing tool engages with the engaging groove on the retrieval puncture needle after having passed from the proximal end to the distal end of the insertion puncture needle together with the engaging member.

3. A tool according to Claim 2, wherein the engaging groove includes a storage recess capable of accommodating the engaging member and an engaged portion with which the upper end portion of the engaging member can engage.

4. A tool according to Claim 2 or 3, wherein the upper end portion of the engaging member is thicker than the lower side portion of the engaging member, the elongate opening of the insertion puncture needle including a wide upper portion through which the upper end portion of the engaging member can pass and a narrow lower portion through which the upper end portion of the engaging member cannot pass and the lower side portion of the engaging member can pass, and the engaging groove of the retrieval puncture needle including a wide upper portion through which the upper end portion of the engaging member can enter and a narrow lower portion through which the upper end portion of the engaging member cannot pass but the lower side portion can enter.

5. A tool according to Claim 4, in which the upper end portion of the engaging member comprises a spherical body and the lower side portion of the engaging member comprises a rod member having smaller diameter than the spherical body.

6. A tool according to Claim 4 or 5, in which an engaging wall is provided at the lower portion of the surface of the wide upper portion of the engaging groove of the retrieval puncture needle so that the upper end portion of the engaging member is prevented from coming off toward the outside from the wide upper portion of the engaging groove.

7. A tool according to any one of Claims 2 to 6, in which the portion on the distal side of the insertion puncture needle with respect to the elongate opening and at least part of the retrieval puncture needle other than the portion where the engaging groove is formed is formed as a solid portion.

8. A tool according to any one of Claims 2 to 7, in which at least a portion of the insertion puncture needle where the elongate opening is formed and of at least a portion of the retrieval puncture needle where the engaging groove is formed are formed into an angular C-shape in lateral cross section, respectively, and are arranged so that the open sides are opposed to each other.

9. A tool according to any one of the preceding Claims, wherein needle points of the insertion puncture needle and the retrieval puncture needle are formed into a pointed conical shape or a tapered thin blade shape.

10. A tool according to any one of the preceding Claims, wherein at least one of the insertion puncture needle and the retrieval puncture needle is formed by connecting a metal member and a resin member.

11. A tool according to any one of the preceding Claims, wherein the insertion puncture needle and the retrieval puncture needle are attached to a retaining member.

12. A tool according to Claim 11, in which the insertion puncture needle and the retrieval puncture needle are detachably attached to the retaining member.

13. A tool according to Claim 11 or 12, wherein the retaining member is constituted of a grip member to be held by a hand.

14. A tool according to any one of Claims 11 to 13, and including a positioning member for regulating the mounting positions of the insertion puncture needle and the retrieval puncture needle with respect to the retaining member.

15. A tool according to any one of Claims 11 to 14, in which a plurality of pairs of the insertion puncture needle and the retrieval puncture needle are provided on the retaining member.

16. A medical suturing tool comprising an insertion puncture needle with a shaft having a proximal end and a pointed distal end, and a retrieval puncture needle with a shaft having a proximal end and a pointed distal end, and a retaining member that connects the respective proximal ends to retain the respective shafts parallel, the insertion needle shaft having an elongate aperture in its wall surface facing the retrieval needle shaft, the retrieval needle shaft having an aperture in its wall surface facing the insertion needle shaft, the respective shafts each defining a lumen from the proximal end to the respective aperture,

the insertion needle lumen containing an elongate lock part long enough to bridge across from the insertion needle aperture to the retrieval needle aperture the insertion needle lumen containing a suture which is attached to the lock part whereby pulling on the suture causes the lock part to emerge from the insertion needle lumen and extend across to the retrieval needle aperture so that, with withdrawal of the retrieval needle, the suture is advanced from the puncture made by the insertion needle to the puncture made by the retrieval needle.

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